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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,272	10/20/2001	Pranela Rameshwar	267/033	8309

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,272	RAMESHWAR, PRANELA	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 21-22, as specifically drawn to an isolated polynucleotide comprising SEQ ID NO:1, a vector, host cell, and pharmaceutical composition, classified in class 536, subclass 23.5; class 435, subclass 325, 320.1, 69.1.

II. Claims 11-12, 14, and 24-25, as specifically drawn to an isolated polypeptide of SEQ ID NO: 2 and a pharmaceutical composition containing the polypeptide, classified in class 530, subclass 350.

III. Claims 13 and 26, as specifically drawn to an isolated antibody immunospecific for the polypeptide of SEQ ID NO:2 and a pharmaceutical composition containing the antibody, classified in class 530, subclass 387.1.

IV. Claims 15-21 and 23, as specifically drawn to a polynucleotide sequence comprising an antisense sequence to a nucleotide of SEQ ID NO: 1 and a pharmaceutical composition containing the antisense, classified in class 536, subclass 24.5.

V. Claims 27-28, as specifically drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a pharmaceutical composition comprising a HGFIN polunucleotide, classified in class 514, subclass 44.

VI. Claims 29-30, as specifically drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by

administering a pharmaceutical composition comprising a HGFIN polypeptide, classified in class 424, subclass 184.1.

VII. Claims 31-32, as specifically drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a pharmaceutical composition comprising a polynucleotide coding for the antisense sequence to SEQ ID NO: 2, classified in class 514, subclass 44.

VIII. Claims 33, as specifically drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a pharmaceutical composition comprising an antibody immunospecific for the HGIFN polypeptide, classified in class 424, subclass 133.1.

IX. Claims 34-36, as specifically drawn to vector for the delivery of an HGFIN therapeutic to a cell for the treatment of leukemia or lymphoma, classified in class 435, subclass 320.1.
(**Upon election of Group IX, the applicant must further choose ONE HGFIN therapeutic from those listed in claim 35, as each HGFIN therapeutic is a distinct invention, NOT a species**)

X. Claims 37-49, as specifically drawn to a method for introducing an HGFIN therapeutic into a cell, comprising transfecting the cell with a vector or plasmid comprising an expression cassette encoding the HGFIN therapeutic, classified in class 435, subclass 320.1.
(**Upon election of Group X, the applicant must further choose ONE HGFIN therapeutic from those listed in claims 43, as each HGFIN therapeutic is a distinct invention, NOT a species**)

XI. Claims 50-56 and 61, as specifically drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula α-HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a radioactive moiety, classified in class 424, subclass 1.73.
(Upon election of Group XI, the applicant must further choose ONE HGFIN sequence from those listed in claim 61, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XII. Claims 50-54, 57-58, and 61, as specifically drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula α-HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a chemotoxic moiety, classified in class 424, subclass 133.1, 185.1.
(Upon election of Group XII, the applicant must further choose ONE HGFIN sequence from those listed in claim 61, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XIII. Claims 50-54 and 59-61, as specifically drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula α-HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a toxin protein moiety, classified in class 424, subclass 133.1, 185.1.
(Upon election of Group XI, the applicant must further choose ONE HGFIN sequence from those listed in claim 61, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XIV. Claim 63, as specifically drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula α-C and a pharmaceutically acceptable carrier, classified in class 424, subclass 1.49.

XV. Claims 64-69 and 74-76, as specifically drawn to a compound for the treatment of a lymphoproliferative disease of the general formula α-HGFIN-C, wherein C is a radioactive moiety, classified in class 424, subclass 1.73.
(Upon election of Group XV, the applicant must further choose ONE HGFIN sequence from those listed in claim 74, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XVI. Claims 64-67, 70-71, and 74-76, as specifically drawn to a compound for the treatment of a lymphoproliferative disease of the general formula α-HGFIN-C, wherein C is a chemotoxic moiety, classified in class 424, subclass 133.1, 185.1.
(Upon election of Group XVI, the applicant must further choose ONE HGFIN sequence from those listed in claim 74, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XVII. Claims 64-67 and 72-76, as specifically drawn to a compound for the treatment of a lymphoproliferative disease of the general formula α-HGFIN-C, wherein C is a toxin protein moiety, classified in class 424, subclass 133.1, 185.1.
(Upon election of Group XVII, the applicant must further choose ONE HGFIN sequence from those listed in claim 74, as each HGFIN sequence is a distinct invention, NOT a species. Applicant should choose between the sense (DNA, cDNA, or RNA) or the antisense)

XVIII. Claim 77, as specifically drawn to a compound for the treatment of a lymphoproliferative disease of the general formula α- C, classified in class 424, subclass 1.49.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV, IX, and XVI-XVIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group I is drawn to an isolated polynucleotide, whereas Group IV is drawn to an isolated antibody.

The invention of Groups V-VIII, and X-XIV are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group V is drawn specifically to a method of treating a disease by administering a pharmaceutical composition, whereas Group X is drawn to a method of introducing an HGFIN therapeutic into a cell by transfecting the cell with a vector or plasmid.

The inventions of Groups I-IV, IX and the method of Group X are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of introducing an HGFIN therapeutic into a cell can be practiced with a materially different material such as a polynucleotide or a polypeptide or an antisense or an antibody or a vector.

The inventions of Groups XVI-XVIII and the method of Group XIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

case the method of treating a lymphoproliferative disease can be practiced with a materially different material such as any one of the formulas disclosed in Groups XVI-XVIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election

Group I and X (Claims 10, 41 and 48) is generic to a plurality of disclosed patentably distinct species comprising bone marrow derived cells such as stem cells, progenitor cells, leukocytes... basophils, blast cells and mast cells which differ at least in morphology and function.

Groups V-VII, XI-XIII (Claims 28, 30, 32, and 51) are generic to a plurality of disclosed patentably distinct species comprising different diseases associated with abnormal bone marrow cell differentiation such as: acute myloid leukemia, acute lymphocytic leukemia, chronic myeloid leukemia, chronic lymphocytic leukemia, Hodgkin's and non-Hodgkin's disease which differ at least in etiology, pathology, and mechanisms.

Group X (Claim 44) is generic to a plurality of disclosed patentably distinct species comprising different transfecting procedures such as calcium phosphate, DEAE-dextran mediated, transvection... use of a gene gun, and liposome transfection which differ at least in route of transfection.

Groups XII and XVI (Claims 58 and 71) are generic to a plurality of disclosed patentably distinct species comprising different chemotoxic moieties such as methotrexate, a pyrimidine analog, a purine analog, a phorbol ester, and butyric acid which differ at least in structural identity.

Groups XIII and XVIII (Claims 60 and 73) are generic to a plurality of disclosed patentably distinct species comprising different toxin proteins such as ricin, abrin, diphtheria toxin, cholera toxin... Shigella toxin, and pokeweed antiviral protein which differ in at least structure, mechanism and toxicity.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant transverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior are, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571)-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER